

dependent diabetes mellitus. Caraco is without information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 5 of the Complaint and therefore, denies them..

6. Caraco denies the allegations of paragraph 6 of the Complaint as inaccurately and incompletely paraphrasing the claims of the '358 patent.

7. Upon information and belief, Caraco admits that Plaintiffs presently market repaglinide under the trademark PRANDIN®.

8. Caraco admits that on December 22, 1997, the U.S. Food and Drug Administration approved PRANDIN® for the “use of repaglinide in combination with metformin to lower blood glucose” and admits upon information and belief, that Novo Nordisk Inc. is the holder of that approval. Caraco denies the remaining allegations of paragraph 8 of the Complaint.

9. Admitted.

10. Admitted.

11. Admitted.

12. Denied.

13. Caraco admits that it imports, offers for sale, and sells metformin in the United States. Caraco denies the remaining allegations of paragraph 13 of the Complaint.

14. Caraco is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 14 of the Complaint and therefore, denies them.

15. Caraco admits that it currently imports, offers for sale, and sells metformin in the United States and that metformin is used as an antidiabetic. Caraco admits that it is

seeking approval to market repaglinide in the United States and that repaglinide is used as an antidiabetic. Caraco denies the remaining allegations of paragraph 15 of the Complaint.

16. Caraco is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 16 of the Complaint and therefore, denies them.

17. Denied.

18. Denied.

19. Denied.

PRAYER FOR RELIEF

In response to Plaintiffs' Prayer for Relief in the Complaint:

a. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (a) of the Prayer for Relief in the Complaint.

b. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (b) of the Prayer for Relief in the Complaint.

c. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (c) of the Prayer for Relief in the Complaint.

d. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (d) of the Prayer for Relief in the Complaint.

e. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (e) of the Prayer for Relief in the Complaint.

f. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (f) of the Prayer for Relief in the Complaint.

g. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (g) of the Prayer for Relief in the Complaint.

h. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (h) of the Prayer for Relief in the Complaint.

i. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (i) of the Prayer for Relief in the Complaint.

j. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (j) of the Prayer for Relief in the Complaint.

k. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (k) of the Prayer for Relief in the Complaint.

l. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (l) of the Prayer for Relief in the Complaint.

m. Sun denies that Plaintiffs are entitled to the relief requested in paragraph (m) of the Prayer for Relief in the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

20. The complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

21. Caraco will not infringe any valid and enforceable claim of the '358 patent under 35 U.S.C. § 271.

THIRD AFFIRMATIVE DEFENSE

22. Upon information and belief, the claims of the '358 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

FOURTH AFFIRMATIVE DEFENSE

23. Plaintiffs fail to state a valid claim for willful infringement.

COUNTERCLAIM

24. Defendant-Counterclaim Plaintiff, Caraco Pharmaceutical Laboratories, Ltd., is a corporation incorporated and existing under the laws of the State of Michigan, and has a principal place of business located at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

25. Plaintiff-Counterclaim-Defendant, Novo Nordisk A/S, is upon information and belief, a Danish corporation having a place of business at Novo Allé, DK-2880 Bagsvaerd, Denmark.

26. Plaintiff-Counterclaim-Defendant, Novo Nordisk, Inc. is upon information and belief, a Delaware corporation having a principal place of business 100 College Road West, Princeton, New Jersey.

27. Caraco has filed Abbreviated New Drug Application (“ANDA”) No. 77-571 for approval to market 0.5 mg, 1 mg, and 2 mg repaglinide tablets in the United States.

28. Caraco sent a notice letter related to ANDA No. 77-571, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to Novo Nordisk A/S and Novo Nordisk, Inc., on April 26, 2005.

29. On or about June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. filed or caused to be filed a Complaint for patent infringement, which alleges that Caraco infringes the ‘358 patent. That complaint was served on Caraco on June 15, 2005.

JURISDICTION AND VENUE

30. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j).

31. Venue in this District is proper under 28 U.S.C. §§ 1391 and 1400.

COUNT I

(Noninfringement of the ‘358 patent)

32. Novo Nordisk A/S claims to be the owner of the United States Patent No. 6,677,358 (“the ‘358 patent”).

33. Novo Nordisk, Inc. claims to be the holder of a New Drug Application for repaglinide tablets.

34. There is an actual, substantial, and continuing justiciable controversy between Caraco and Plaintiffs-Counterclaim Defendants, Novo Nordisk A/S and Novo Nordisk, Inc., regarding the infringement, validity, and enforceability of the ‘358 patent.

35. Caraco will not infringe any valid and enforceable claim of the '358 patent under 35 U.S.C. § 271.

36. Caraco is entitled to a declaration that it will not infringe any valid and enforceable claim of the '358 patent.

COUNT II

(Invalidity of the '358 patent)

37. Defendant-Counterclaim Plaintiff Caraco repeats and realleges all of its allegations in paragraphs 23-35 of its Counterclaim as if each were separately set forth at length herein.

38. Upon information and belief, the claims of the '358 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

39. Caraco is entitled to a declaration that all claims of the '358 patent are invalid, void, and/or unenforceable.

PRAYER FOR RELIEF


WHEREFORE, Caraco prays that the Court enter:

- A. A declaratory judgment that Caraco will not infringe any valid and enforceable claim of the '358 patent under 35 U.S.C. § 271;
- B. A declaratory judgment that the '358 patent is invalid, void, and or unenforceable;
- C. An Order enjoining and restraining Novo Nordisk A/S and Novo Nordisk, Inc. and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from further charges of infringement or acts of enforcement based on the

'358 patent against Caraco, its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Caraco; and

D. An Order awarding Caraco such other further relief as the Court deems just and equitable.

Dated: July 21, 2005


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Attorneys for Defendant-Counterclaim Plaintiff
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CERTIFICATION

I hereby certify that on July 21, 2005, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to the following: **Eric S. Goldstein, James F. Hunt and Joseph R. Robinson**. Parties may access this filing through the Court's system.

A handwritten signature in black ink, appearing to read "Morley Witus", is written over a horizontal line.

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